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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/622,703	08/21/2000	Warren Hoeffler	XGEN-110-USA	8907

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EXAMINER

CHAKRABARTI, ARUN K

ART UNIT PAPER NUMBER

1634

DATE MAILED: 08/14/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory ActionApplication No.
09/622,703Applicant(s)
HoefflerExaminer
Arun ChakrabartiArt Unit
1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Aug 6, 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s):

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See attached sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____
Claim(s) objected to: _____
Claim(s) rejected: _____
Claim(s) withdrawn from consideration: _____
8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

Applicant's arguments and request for reconsideration filed on August 8, 2002 have been fully considered but they are not persuasive and therefore do not place the application in condition for allowance.

Applicant argues that 102 (b) rejection based on Gansz et al. (Molecular and General Genetics, (1991), Vol. 225, pages 427-434) should be withdrawn because no positive correlation between nicking of DNA and transcription has been demonstrated by the reference. This argument is not persuasive. Applicant argues that Gansz et al. reference does not teach the correlation between nicking of DNA and transcription of the claimed invention. Applicant argues that the word "correlation between nicking of DNA and transcription" was not found in Gansz reference and only the words "have no explanation" and "might be responsible" are found. Applicant argues that because Gansz has a preferred embodiment of speculation, Gansz is limited to the preferred embodiment. This argument is not persuasive. As MPEP 2123 states "Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 169 USPQ 423 (CCPA 1971)." MPEP 2123 also states "A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including nonpreferred embodiments. Merck & Co. v. Biocraft Laboratories, 10 USPQ2d 1843 (Fed. Cir. 1989)." It is clear that simply because Gansz has a preferred embodiment, this embodiment does not prevent the reference from suggesting broader embodiments in the disclosure and that this does not constitute a teaching away. Although Gansz reference uses speculative terms e.g., "might be responsible" or "might contribute" to explain the results of their invention, the property of transcription as a result of nicking is inherently present in this chemically and structurally identical molecule. For example, Gansz reference clearly teaches that such nicks "contribute to activation of the template for late transcription" (Page 428,

column 1, lines 6-7). Moreover, MPEP 2111 states, "Claims must be given their broadest reasonable interpretation. During patent examination, the pending claims must be "given the broadest reasonable interpretation consistent with the specification". Applicant always has the opportunity to amend the claims during prosecution and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than it is justified. *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-51 (CCPA 1969)". In this case, any nicks of DNA under any suitable conditions can be attributed to the transcription as clearly taught and suggested by Gansz.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant also argues that there is lack of motivation to combine the references. This argument is not persuasive, especially in the presence of strong motivation provided by Hodgson et al. since Hodgson et al. state, "Within the promoter sequence will be found a transcription initiation site conveniently defined by mapping with nuclease S. (Column 5, lines 22-24)." This logic is applicable to other 103 (a) rejection as well.

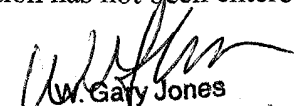
Applicant then argues the 103 rejection is improper because it lacks a reasonable expectation of success.

With regard to the "lack of reasonable expectation of success", the MPEP 2143.02 states "Obviousness does not require absolute predictability, however, at least some degree of predictability is required. Evidence showing there was no reasonable expectation of success may support a conclusion of nonobviousness. *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA

1976) (Claims directed to a method for the commercial scale production of polyesters in the presence of a solvent at superatmospheric pressure were rejected as obvious over a reference which taught the claimed method at atmospheric pressure in view of a reference which taught the claimed process except for the presence of a solvent. The court reversed, finding there was no reasonable expectation that a process combining the prior art steps could be successfully scaled up in view of unchallenged evidence showing that the prior art processes individually could not be commercially scaled up successfully.). See also *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir.), cert. denied, 502 U.S. 856 (1991) (In the context of a biotechnology case, testimony supported the conclusion that the references did not show that there was a reasonable expectation of success. 18 USPQ2d at 1022, 1023.); *In re O'Farrell*, 853 F.2d 894, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988) (The court held the claimed method would have been obvious over the prior art relied upon because one reference contained a detailed enabling methodology, a suggestion to modify the prior art to produce the claimed invention, and evidence suggesting the modification would be successful.)."

There is no evidence of record submitted by applicant demonstrating the absence of a reasonable expectation of success. There is evidence in the Gansz reference of the enabling methodology, the suggestion to modify the prior art, and evidence that a number of different nicks in the DNA of T4 bacteriophage were actually experimentally studied and found to be functional to enhance transcription (Abstract and Page 428, column 1, lines 2-7). This evidence of functionality trumps the attorney arguments, which argues that Gansz reference is an invitation to research, since Gansz steps beyond research and shows the functional product.

In view of the response to argument, all rejections as made in the last office action are hereby properly maintained. Accordingly, the request for reconsideration has not been entered.


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600